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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
| 10/673,167 | 09/30/2003 | Lloyd Marks | 117622-00102 | 9810 |
| 27557 7590 08/24/2007 BLANK ROME LLP 600 NEW HAMPSHIRE AVENUE, N.W. WASHINGTON, DC 20037 | | | EXAMINER TOTH, KAREN E | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3735 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/673,167

Applicant(s)

MARKS ET AL.

Examiner

Karen E. Toth

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 May 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-61 is/are pending in the application.
- 4a) Of the above claim(s) 1-24 and 28-55 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-27 and 56-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 25 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 25 recites the limitation of calculating one of a peak net inflow, area under a curve, or pulse volume x heart rate product; applicant has not disclosed how or where the calculations of peak inflow or the area under the curve would be used if measured.

Claim Rejections - 35 USC § 103

4. Claims 24-26, 56, 57 are rejected under 35 U.S.C. 102(b) as being anticipated by Raines (US Patent 6149587) in view of Stephens (US Patent 3796213).

Regarding claims 24, 25, 58, and 61, Raines discloses a method for detecting peripheral vascular disease (that is, a physical condition) comprising taking quantitative pulse volume measurements at a plurality of positions on the patient's limbs (column 4, lines 43-49; column 6, lines 32-35; column 7 line 63 to column 8 line 5); and detecting the peripheral vascular disease from the quantitative pulse volume measurements

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(column 2 line 66 to column 3 line 14). The examiner notes that Raines does not explicitly disclose diagnosing vascular disease. However, based upon the discussion provided in the background of the patent, and the fact that Raines generates a vascular diagnosis based upon pulse volume inputs from a plurality of cuffs, it is clear that the vascular diagnosis that the system provides would be the diagnosis of vascular disease. Raines does not disclose using the produce of a pulse volume x heart rate calculation to diagnose the peripheral vascular disease, though both measurements are taken during the method (the heart rate may be obtained from either the pulse volume recorder signal or the photoplethysmograph signal).

Stephens teaches a method of diagnosing peripheral vascular disease by measuring pulse volume and performing signal averaging (column 2, lines 1-9) and then calculating pulse volume x heart rate (column 1, lines 14-19; column 2, lines 50-55), in order to accurately diagnose the patient's condition. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Raines and diagnosed peripheral vascular disease by multiplying the pulse volume by a heart rate, as taught by Stephens, in order to accurately diagnose the patient's condition.

Regarding claims 26 and 59, Raines further discloses that the measurements may be taken at different times and compared (column 6, lines 14-18) in order to determine the disease's current status (column 6, lines 1-3).

Regarding claim 56, Raines further discloses comparing the quantitative pulse volume measurements among the plurality of positions on the patient's limbs (figures 15-18).

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Regarding claim 57, Raines further discloses comparing the quantitative pulse measurements for different limbs of the patients (column 7, lines 36-50).

5. Claims 27 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Raines in view Stephens, and further in view of Huizenga (US Patent Application Publication 2004/0043614).

Raines in view of Stephens discloses all the elements of the current invention, as described above, except for the method being performed both before and after a peripheral vascular disease treatment or stimulus in order to determine the efficacy of the treatment.

Huizenga teaches a method of detection of peripheral vascular disease where the vascular disease detection is performed both before and after treatment in order to determine the efficacy of the treatment (paragraphs [0023] and [0047]), so that a health care provider can determine if an alternate treatment is needed. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have followed Raines in view of Stephens and measured the patient's vascular disease status both before and after treatment to determine the treatment's efficacy, as taught by Huizenga, so that a health care provider can determine if an alternate treatment is needed.

Response to Arguments

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6. Applicant's arguments with respect to claims 24-27, 56, and 57 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP.

§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen E. Toth whose telephone number is 571-272-6824. The examiner can normally be reached on Monday through Friday.

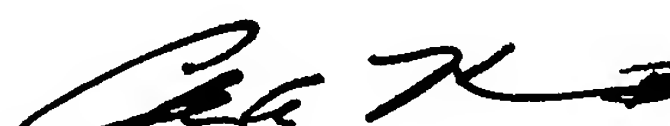
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Charles Marmor, II can be reached on 571-272-4730. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


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